REMARKS

In the Office Action dated February 28, 2000, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121 as follows:

I. Claims 1-29, drawn to a non-pathogenic HIV-1 strain, classified in class 435, subclass 236.

II. Claims 30-48 and 85, drawn to a method of inhibiting HIV-1 infection by administering a therapeutic composition comprising non-pathogenic HIV-1 isolate, classified in class 424, subclass 208.1.

III. Claims 49-67 and 85, drawn to a method of vaccinating elected subjects with a therapeutic composition comprising a non-pathogenic HIV-1 isolate, classified in class 424, subclass 208.1.

IV. Claims 68-79, drawn to a method for the preparation of non-pathogenic HIV-1 isolates from biological samples, classified in class 435, subclass 237.

V. Claims 80-82, drawn to a screening method for the identification of putative antiviral compounds employing a new fusion protein, classified in class 435, subclass 7.1.

VI. Claims 83-84, drawn to compound capable of inhibiting nef gene activity, classified in class 424, subclass 278.1.

VII. Claims 86, drawn to a therapeutic composition comprising a non-pathogenic HIV-1 isolate that is also capable of expressing a ribozyme or antisense molecule, classified in class 536, subclass 24.5.

VIII. Claims 87-93, drawn to a non-pathogenic viral isolate comprising a modified genome capable of expressing an antisense or ribozymal molecule that inhibits HIV-1 replication, classified in class 424, subclass 93.2.

IX. Claims 94-110 and 115, drawn to a method for determining the pathogenicity of an HIV-1 strain

through the detection of deletion mutations in the viral genome, classified in class 435 subclass 91.2.

X. Claims 111-114 and 116, drawn to a method for determining the pathogenicity of an HIV-1 strain by employing a peptide-based assay, classified in class 435, subclass 34.

XI. Claim 117, drawn to a peptide comprising SEQ ID NO.: 801 or a fragment thereof, classified in class 530, subclass 326.

XII. Claim 118, drawn to antibodies that bind to a peptide comprising SEQ ID NO.: 801 or a fragment thereof, classified in class 530, subclass 387.1.

XIII. Claim 119, drawn to a method of risk assessment employing a peptide defined SEQ ID NO.: 801, classified in class 436, subclass 506.

The Examiner has alleged that the subject matter defined by the claims of the present invention represents the foregoing thirteen separate and distinct inventions.

In the first instance, the Examiner alleges that Groups I, VI-VIII, XI and XII are unrelated, as the Examiner contends that each of these groups is directed toward a different product (i.e., non-pathogenic HIV-1 isolate, antiviral compound therapeutic composition, modified non-pathogenic HIV-1 isolate, peptide, and antibody, respectively) with a different structure and function.

The Examiner further alleges that Groups II-V, IX, X, and XIII are unrelated, as the Examiner contends that each of these groups is directed toward a different methodology (methods of inhibiting viral infection, methods of vaccinating subjects, methods of preparing viral isolates, methods of screening

antiviral compounds, methods for determining viral pathogenicity, and methods of risk assessment, respectively) that employs different reagents and methodology steps toward a different objective.

The Examiner admits that Groups I and II/III, Groups I and IV, and Groups XI and XIII are related as product and process of use, respectively. However, the Examiner contends that these groups are patentably distinct inventions since the products of Groups I and XI can be employed in a number of different methodologies other than those in Groups II-IV and XIII, and the methods of Groups II-IV and XIII can be practiced with a product different from those of Groups I and XI.

The Examiner next alleges that Groups I, VI-VIII and XI-XII are unrelated to Groups II-V, IX-X and XIII except where noted in the preceding paragraph. The Examiner contends that none of the products are required to practice the methodologies and the methodologies do not require any of the identified products in order to be performed.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect to prosecute the subject matter of Claims 49-67 and 85, directed to methods of vaccinating subjects with a therapeutic composition comprising a non-pathogenic HIV-1 isolate. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application.

However, pursuant to 37 C.F.R. §§ 1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added).

The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized.

In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement. Applicants submit that Group I is directed to non-pathogenic HIV-1 isolates, that the compounds, molecules or compositions of Groups VI-VII and XI-XII are made by using the non-pathogenic HIV-1 isolates of Group I, and that the methods of Groups II-V, IX-X and XIII are directed to the making and using of the non-pathogenic HIV isolates of Group I, or the making and using of the compositions made by employing the viral isolates of Group I.

Thus, Applicants submit that Groups I-XIII are clearly interdependent.

Applicants further submit that the interdependence of Groups I-XIII is confirmed --indeed, it is mandated-- by virtue of the fact that 35 U.S.C. §112 compels disclosure of all aspects of the invention in the one application which applicants have filed. For example, an application claiming the HIV-1 isolates containing deletions in Nef or the LTR is required to disclose inter alia how to make and use that invention. In other words, a description of the means and method for producing and using the subject HIV-1 isolates is a mandatory part of the application. Indeed, if any of these aspects of a complete disclosure were omitted, the application could be considered defective under §112, first paragraph. Consequently, it is clear that aspects of a given invention, such as a product, its use, and the process of producing that product, are necessarily interdependent, not independent, from each other.

The courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

The Examiner also states that the inventions have acquired a separate status in the art as evidenced by the separate classification and recognized divergent subject matter and would require independent searches. Thus, the Examiner concludes that restriction for examination purposes is proper. Reliance on the supposed classification of the groups of claims does not establish independence and distinctness. The classification system has no statutory recognition as evidence of whether inventions are independent and distinct. The classification system is instead an aid in finding and searching for patents.

The classification system is also an unreliable basis for requiring restriction between claims to the various aspects of applicants' unitary invention, because the system exhibits considerable overlap in technical definitions. In particular, the definitions of classes and subclasses in the classification system do not prevent the Examiner from basing patentability decisions, as to claims assigned to one group, on patent references found in the classes or subclass(es) with which he associated another group of claims.

Furthermore, the classification system is a poor basis for requiring restriction between related aspects of an invention because classifications and definitions change over time. Thus, a classification that might have seemed to support restriction at a given time could change, thereby casting a shadow over the propriety of the restriction requirement later on during the term of the patents issuing from parent and divisional applications. Indeed, classifications seem largely to change in response to considerations of administrative convenience, and often in response to nothing more than growth in the number of patents in a given class or subclass. These considerations have nothing to do with whether the subject matter of patents assigned to different classifications is "independent and distinct" as those terms are used in 35 U.S.C. §121, which fact proves that basing restriction requirements on the classification system is improper.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring

excessive filing costs or to otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,

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